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EXAMINER

TRAVERS, RUSSELL S

| ART UNIT | PAPER NUMBER |
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1617

10

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,453

Applicant(s)

LACADIE ET AL.

Examiner

Russell Travers, J.D., Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The election filed November 4, 2003 has been received and entered into the file.

Claims 1-19 are presented for examination.

Applicant's election without traverse of Group I, claims 1-12, 18-19 in Paper No. 7 is acknowledged.

Claims 13-17 reading on non-elected subject matter are withdrawn from consideration.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

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- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth criteria that defines neither "component A" which is an "aryl functional group" nor "component B" which is an "aromatic nitrogen containing herteroaryl functional group" suitable to practice the invention as claimed.

Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of compounds which contain an "aryl functional group" or an "aromatic nitrogen containing herteroaryl functional group" suitable to practice the invention as claimed examples are set forth, thereby failing to provide sufficient working examples.

It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all compounds possessing an "aryl functional group" or an "aromatic nitrogen

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containing herteroaryl functional group" suitable to practice the invention as claimed, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-4, 6-10 and 12 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-4, 6-10 and 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-10 and 12 are rendered indefinite by the phrases "aryl functional group" and "aromatic nitrogen containing herteroaryl functional group" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are serve as an "aryl functional group" or a "aromatic nitrogen containing herteroaryl functional group" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

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Claims 3 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 9 are rendered indefinite by setting forth an R_2 substituant and failing to define those chemical structures encompassed by this substituant and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Applicant's designation fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals & Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApl's 1989) at 2303, as to where broad language is followed by "such as" and then narrow language. The Board stated, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claims 1-12 recite the broad recitation of HIV, HCMV and HHV, and these claims also recite, Retroviral, which is a narrower statement of the range/limitation. Applicants recitation of the broad range or limitation together with a narrow range or limitation renders independent claims 1 and 7, and dependant claims 2-6 and 8-12 properly rejected as indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-7 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Elks et al.

Applicants' attention is directed to Elks et al, table II, example 10, setting forth compounds encompassed by the instant claimed subject matter. Elks et al teach such compounds as useful for inhibiting herpes virus, indistinguishable from those etiological agents herein claimed.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-12 and 18-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Elks et al, Wood and Markley et al

Elks et al, Wood and Markley et al teach the claimed compounds, see table II and claims 1, respectively, as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating viral infections, to include herpes infections viewed by the skilled artisan as those etiological agents herein claimed. Claims 2, 4-5, 8-11 and 18-19 and the primary references, differ as to:

- 1) employment of these medicaments for treating specific virus, and
- 2) administration of the specific medicaments to treat the viral conditions.

It is generally considered prima facie obvious to employ antiviral medicaments broadly and enjoy a reasonable expectation of therapeutic success. Attention is drawn to Elks et al teaching compounds herein claimed as useful for treating herpes virus. Markley et al teach those compounds herein claimed (see claim 1 when $m=0$, $q=1$ and

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R= substituted ArCH_2) as possessing broadly antiviral properties (see column 33, lines 25-30). Possessing these teachings the skilled artisan would have been motivated to employ the prior art compounds to treat the recited etiological agents and enjoy a reasonable expectation of therapeutic success.

Claims 6 and 12 specifically requires a pharmaceutical composition. Wood and Markley et al employed the claimed compounds in various formulations, not specifically reciting a specific formulation. The skilled artisan would have seen therapeutic compositions, and the administration of these compounds by conventional means as residing in the skilled artisan purview.

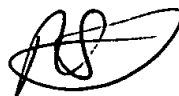
The skilled artisan, possessing a compound for an old and well known therapeutic use possesses that compounds isomers, analogs, homologs, bioisosteres for the same use. Attention is directed to *In re Ward* 141 USPQ 227 (CCPA 1964) and *Galaxo Operations U.K. Ltd. V. Quigg* 13 USPQ2d 1628, setting forth guidelines regarding therapeutic compounds relationships. Those compounds taught as obvious over the therapeutic compound are acids, ethers, esters and all salts. In the instant case, Applicants attempt to capture these obvious variants of the old and well known therapeutic compounds. Absent an illustration of unexpected benefits residing in the specific compounds herein claimed, the instant claims remain properly rejected under 35 USC 103. Attention is directed Markley et al teach those compounds herein claimed (see claim 1 when $m=0$, $q=1$ and R= substituted ArCH_2) as possessing broadly antiviral

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properties (see column 33, lines 25-30) and thereby setting forth compounds residing in claims 1-4, 6-10 and 12. As stated above, possessing a compound for a specific therapeutic use, the skilled artisan possesses those compounds analogs and homolog for the same therapeutic use.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

A handwritten signature in black ink, appearing to be 'RT' or similar initials, enclosed within a circular or oval shape.

Russell Travers J.D., Ph.D.
Primary Examiner
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